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(71) Applicant *(for all designated States except US)*: **UNOMEDICAL A/S** [DK/DK]; Birkerød Kongevej 2, DK-3460 Birkerød (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **GYRN, Steffen** [DK/DK]; Brogade 12, 3, DK-4100 Ringsted (DK). **MATHIASEN, Orla** [DK/DK]; Lønnevang 8, DK-4180 Sorø (DK).

(74) Agent: **NILAUSEN, Kim**; Zacco Denmark A/S, Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).

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(54) **Title**: INSERTER FOR TRANSCUTANEOUS DEVICE

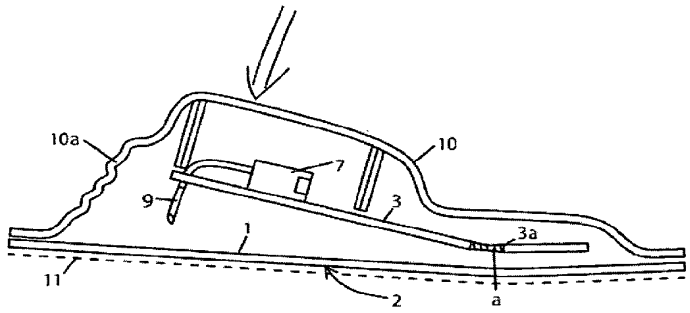

Fig. 3A

(57) **Abstract**: The present application relates to a device comprising a transcutaneous device and an inserter which transcutaneous device has a mounting surface. The device is upon delivery arranged in a sterile packing which packing functions as inserter and is attached to the transcutaneous device i.e. the packing and the inserter is one integrated unit. A device comprises a transcutaneous device and an inserter. The transcutaneous device comprises - a mounting part (1) having a mounting surface (2), - a hard cannula (9) - a fluid path leading fluid from a fluid source to the hard cannula (9), The inserter comprises - a packing (10) at least partly covering the transcutaneous device before use which packing (10) comprises — a non-deformable portion which portion cannot be deformed by the user during normal use and — a deformable portion (10a) which portion can be reduced lengthwise in the direction of insertion during use. Preferably the mounting surface (2) is at least partly adhesive.

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Inserter for transcutaneous device

Technical field

The present invention relates to a device comprising a transcutaneous device and an inserter which transcutaneous device has a mounting surface. The device is upon delivery arranged in a sterile packing which packing functions as inserter and is attached to the transcutaneous device i.e. the packing and the inserter is one integrated unit.

Prior art

WO 2007/141210 discloses an assembly comprising a skin mountable device and a packing for this device. The packing of this device can be attached to the enclosed skin mountable device and then the packing can be used as an applicator for mounting the skin mountable device on the skin surface of the patient. When the packing is pushed in the direction of the housing i.e. along the skin surface, the packing will become detached from the skin mountable device. A body portion comprises a housing portion in which a cannula inserting mechanism is arranged i.e. the cannula inserting mechanism is not part of the packing and the cannula inserting mechanism according to this document is complex and comprises a coil-formed tension spring.

Summary of the invention

The present invention relates to a device comprising a transcutaneous device and an inserter. The transcutaneous device comprises a mounting part having a mounting surface, a hard cannula, a fluid path leading fluid from a fluid source to the hard cannula. The inserter comprises or is constituted of a packing at least partly covering the transcutaneous device before use which packing comprises a non-deformable portion which portion cannot be deformed by the user during normal use and a deformable portion which portion can be reduced lengthwise in the direction of insertion during use.

That the inserter and the packing is constituted by the same piece(s) of material means that the amount of waste will be reduced and there will be fewer units for the user to handle.

According to one embodiment the mounting surface is at least partly adhesive and normally the mounting surface will be covered by a release liner before use in order to protect the adhesive surface(s). That the mounting surface is at least partly adhesive means that it might only be selected areas on the mounting surface which is provided with adhesive.

According to one embodiment the release liner can constitute a part of the packing covering and adhesive surface of the transcutaneous device before use.

According to one embodiment a hard plate is attached to the mounting part and this hard plate can be provided with a linear part of flexible material dividing the hard plate into a first part and a second part where the second part is fixed to the mounting part and the first part can pivot around an axis a formed by the linear flexible material. The hard plate can also have areas of soft flexible material e.g. around the insertion point of the cannula.

According to this embodiment an angle α between the first part and the second part in a first position can be smaller than 90 degrees and larger than the angle defined by the length of the hard cannula (9) which is to be inserted.

According to one embodiment the hard cannula can be made of steel or hard plastic.

According to one embodiment the fluid source is a reservoir attached to the mounting part.

According to one embodiment the packing can be formed of a hard deformable plastic e.g. of two or more types of hard plastic having different ability to be compressed i.e. having the extent of the material reduced.

According to one embodiment the mounting part can be provided with two at least partly adhesive surfaces, one surface facing the inserter packing and the mounting surface. This makes it possible place and adhere the device to the patients skin and then afterwards adhere the transcutaneous device to the opposite surface of the mounting part.

According to one embodiment the reservoir can contain insulin.

Detailed description of the invention

Embodiments of the invention will now be described with reference to the figures in which:

Figure 1 shows an embodiment of a transcutaneous device seen from above after it has been positioned on the patients skin.

Figure 2 shows an enlargement of a cannula in a second embodiment of a transcutaneous device seen from the side.

Figure 3a and 3b shows a cannula of figure 2 placed in a transcutaneous device in a first position (fig. 3a) before insertion of the cannula and a second position (fig. 3b) after insertion of the cannula.

Figure 4 shows a transcutaneous device placed on a patients skin having a pumping part partly mounted.

Figure 5a and 5b show a second embodiment of a packing in a first position (fig. 5a) before insertion of the cannula and a second position (fig. 5b) after insertion of the cannula.

Figure 6a-6f show a third embodiment of a packing/inserter going through the steps of positioning, insertion and putting into work.

Fig. 1 shows a first embodiment of a transcutaneous device comprising a cannula which can be inserted with the inserter of the present invention. The inserter could also be used e.g. for vaccinations where a single dose of medication has to be injected. The transcutaneous device comprises a mounting part 1 having a mounting surface 2 which is not shown on this figure as the mounting surface is turned towards the patient and is in contact with the patient after mounting of the device. The mounting part 1 can be made of a compliant material which is able to adjust to the

patients skin surface and the mounting surface can be an adhesive partly or fully covering the lower side of the mounting part i.e. the side of the mounting part 1 which is turned towards the patient during use. According to one embodiment the mounting part 1 comprises adhesive on both the upper and lower side i.e. on both the mounting surface 2 and the opposite surface. Also the mounting part 1 can be provided with portions of softer and more flexible material (shown as a shaded area around the cannula part). The softer and more flexible material can e.g. be TPE.

A plate 3 of a harder and less flexible material is fastened to the top of the mounting part 2. This plate 3 has been provided with two rails 4a and 4b which rails correspond to grooves or hooks in a corresponding cover 5 for the transcutaneous device. The cover 5 can comprise a pump and means for administrating correct amounts of medication. A reservoir 6 can also be attached either directly or indirectly to the plate 3. If the reservoir 6 is attached indirectly to the plate it will be attached to a connector part 7 via a connector needle 8. The connector part 7 provides a fluid path to a cannula 9 and can be made of e.g. PUR or TPE. The cannula 9 is made of a hard material and is provided with a pointed end which end can cut through the skin. A "hard material" is a material which is hard enough to penetrate the skin surface of the patient and maintain its original shape. According to one embodiment the cannula is a steel needle – G29 and 5 mm long. Normally the needle is less than 10 mm long, where the length is the extent beyond the patients skin.

Fig. 2 shows an enlargement of a second embodiment of a part of a transcutaneous device. The cannula 9 comprises a bend needle made of a hard material which could e.g. be either steel or a hard plastic. The connector part 7 is attached to the plate 3 which plate 3 is provided with an area of a soft and flexible material 3a. In the area of the soft and flexible material 3a the plate 3 can e.g. be able to bend along the line formed by the soft material. This soft and flexible material can e.g. be a layer of TPE.

Fig. 3a and 3b show the cannula part of fig. 2 positioned on a transcutaneous device. The transcutaneous device is placed in a packing according to an embodiment of the invention. The packing is formed of a hard top 10 combined with a compressible part 10a, such a packing can be made of more than one material but alternatively the

different characteristics of the parts 10 and 10a can also be achieved by varying the form of the material i.e. the material can be corrugated in the compressible part 10a or by varying the thickness of the material i.e. the material can be thinner in the compressible part 10a. A suitable material for the packing would e.g. be PP. Fig. 3a shows the transcutaneous device and the packing the positions they have before insertion and fig. 3b shows the two units in the positions they have after insertion of the cannula.

Before insertion the packing forms a closed sterile room in which the transcutaneous device is kept, the sterile room is formed as the top 10, 10a of the packing is joined air tight to the mounting part 1.

The packing 10 of the shown embodiment comprises an area of corrugated material 10a which area can be compressed in the direction of insertion i.e. the size of the packing 10 is reduced in this direction. In areas where the packing 10 is not corrugated it is made of a material and in a shape which assures that the packing does not change its dimension during normal use and storing. When a user intends to use the device, the user first removes a release liner 11 which release liner 11 protects the adhesive mounting surface 2 which is fasten the transcutaneous device to the patient during use, then the user pushes the packing 10 down toward the skin of the patient . When the packing 10 is pushed toward the skin, a first part of the plate 3 is in contact with the patients skin and in a fixed position while a second part of the plate 3 is lifted away from the patients skin as the plate 3 is bend around an axis a parallel to the portion of flexible material 3a in the plate 3. When the user wants to insert the cannula 9, the user pushes down on the top of the packing 10 as indicated with an arrow. This movement makes the second part of the plate 3 pivot around the axis a and straightens out the plate 3 and the cannula 9 penetrates first the mounting part 1 and then the patients skin. At last the packing 10 is detached from the transcutaneous device and disposed of. As the packing and the inserter is constituted by the same material the amount of waste is reduced compared to similar products were the inserter is a separate unit.

Fig. 4 shows the transcutaneous device of fig. 1 after the cannula 9 has been inserted transcutaneously in the patients skin. The transcutaneous device is partly covered by a cover which is half way into its end position, in order to bring the cover 5 to its end and working position it has to be pushed forward in the direction of the arrow. The connector needle 8 of the reservoir 6 can be seen below the cover 5 and when the cover 5 is in the working position, the connector needle 8 has penetrated the protective layer covering the inlet of the connector part 7. The device can be used by patients suffering from diabetes, and then the reservoir 6 will contain insulin.

Fig. 5a and 5b show a second embodiment of an inserter according to the invention. The transcutaneous device cannot be seen as it is fully covered by the packing. According to this embodiment, the packing 10 has the form of a box where the corrugated part 10a of the packing 10 is placed along the sides of box. When the inserter-packing has been placed on the patients skin and is to be activated, the user pushes the protective top down and thereby causes the not shown cannula of the transcutaneous device to be inserted. This embodiment of the inserter can be made as a two component injection molded package.

Fig. 6a-6f show a third embodiment of an inserter according to the invention. The reference numbers refer to the same parts as in the earlier described embodiments
Fig. 6a shows the closed packing provided with a release liner 11 before use.
Fig. 6b shows the closed packing without release liner 11 ready for use.
Fig. 6c shows the closed packing after insertion of the hard cannula 9.
Fig. 6d shows the transcutaneous device after insertion of the cannula 9 and after the packing/inserter has been removed.
Fig. 6e shows the transcutaneous device in a position where the cover – in this case provided with a pump and controller and a fluid reservoir 6 – is half way in end position.
Fig. 6f shows the transcutaneous device in its final working position where fluid is delivered to the patient.

Claims

1. A device comprising a transcutaneous device and an inserter which transcutaneous device comprises
- a mounting part (1) having a mounting surface (2),
- a hard cannula (9)
- a fluid path leading fluid from a fluid source to the hard cannula (9),
said inserter comprising
- a packing (10) at least partly covering the transcutaneous device before use which packing (10) comprises
-- a non-deformable portion which portion cannot be deformed by the user during normal use and
-- a deformable portion (10a) which portion can be reduced lengthwise in the direction of insertion during use.

2. Device according to claim 1, wherein the mounting surface (2) is at least partly adhesive.

3. Device according to claim 2, wherein the mounting surface (2) is covered with a release liner (11).

4. Device according to claim 3, wherein the release liner (11) constitutes a part of the packing covering and adhesive surface of the transcutaneous device before use.

5. Device according to any of the preceding claims, wherein a hard plate (3) is attached to the mounting part (1).

6. Device according to claim 5, wherein the hard plate (3) is provided with a linear part of flexible material (3a) dividing the hard plate (3) into a first part and a second part where the second part is fixed to the mounting part (1) and the first part can pivot around an axis a formed by the linear flexible material (3a).

7. Device according to claim 6, wherein an angle α between the first part and the second part in a first position is smaller than 90 degrees and larger than the angle defined by the length of the hard cannula (9) which is to be inserted.

8. Device according to any of the preceding claims, wherein the mounting part (1) is provided with a flexible part around the insertion point of the cannula (9).

9. Device according to any of the preceding claims, wherein the hard cannula (9) is made of steel or hard plastic.

10. Device according to any of the preceding claims, wherein the fluid source (6) is a reservoir attached to the mounting part (1).

11. Device according to any of the preceding claims, wherein the packing (10, 10a) is formed of a hard deformable plastic e.g. of two or more types of hard plastic having different ability to be compressed..

12. Device according to any of the preceding claims, wherein the mounting part (1) is provided with two at least partly adhesive surfaces, one surface facing the inserter packing (10, 10a) and the mounting surface (2).

13. Device according to any of the preceding claims, wherein the reservoir (6) contains insulin.

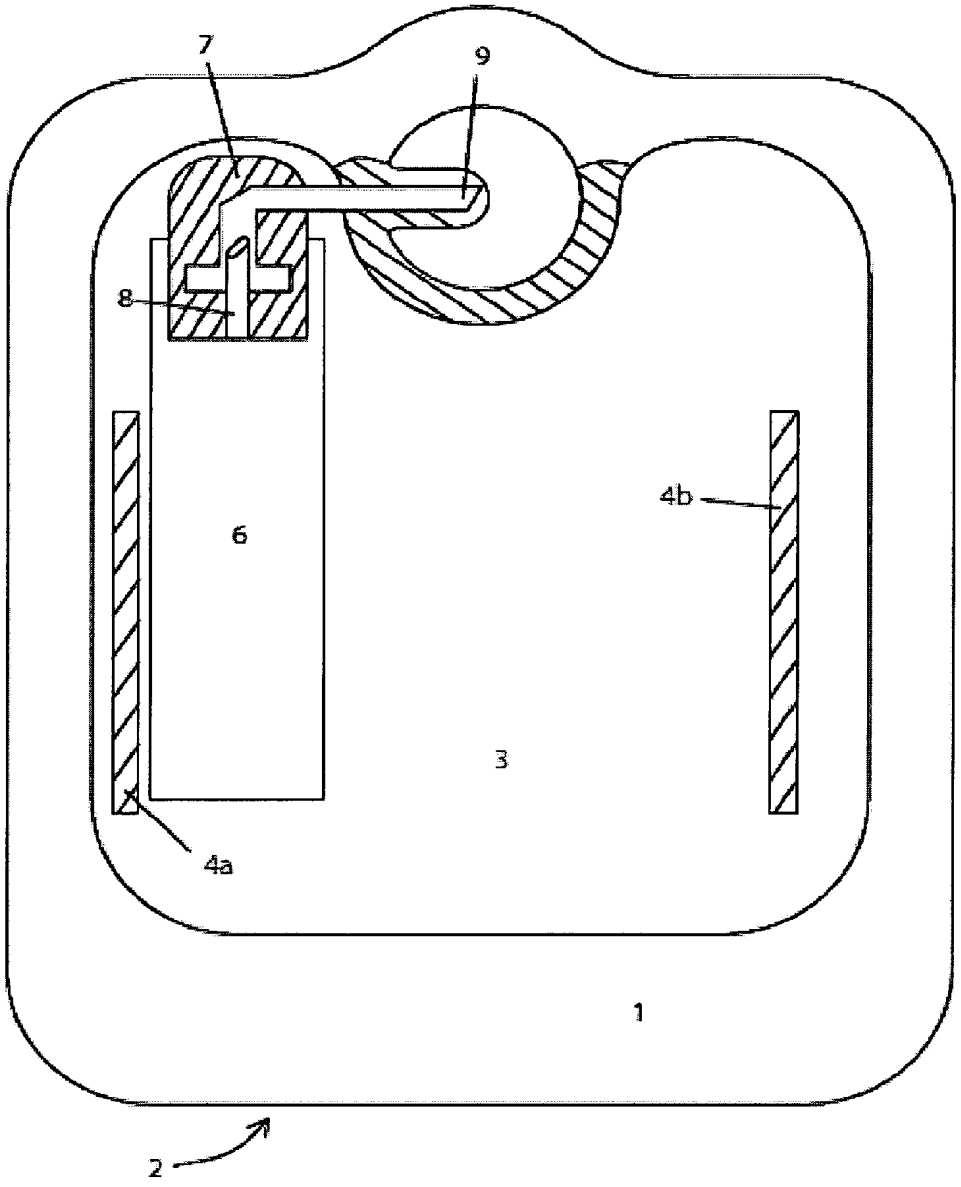

Fig. 1

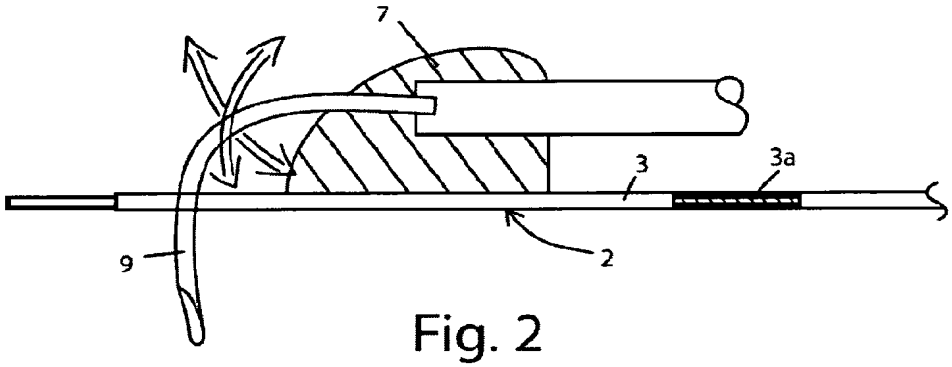

Fig. 2

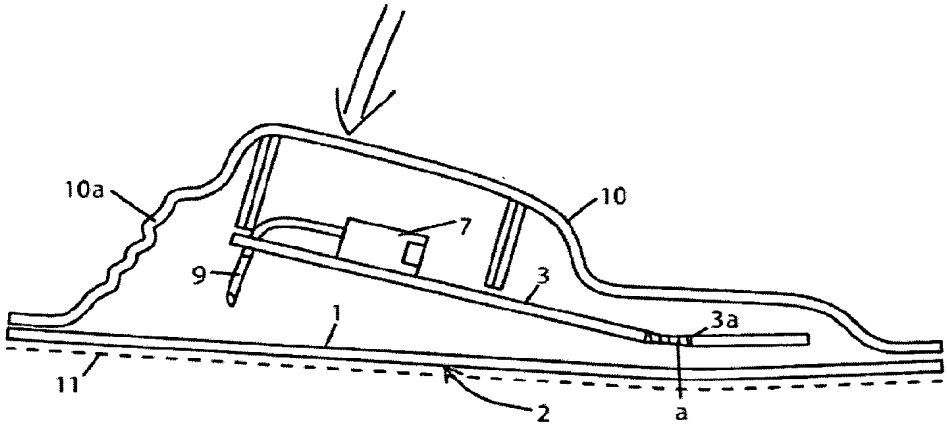

Fig. 3A

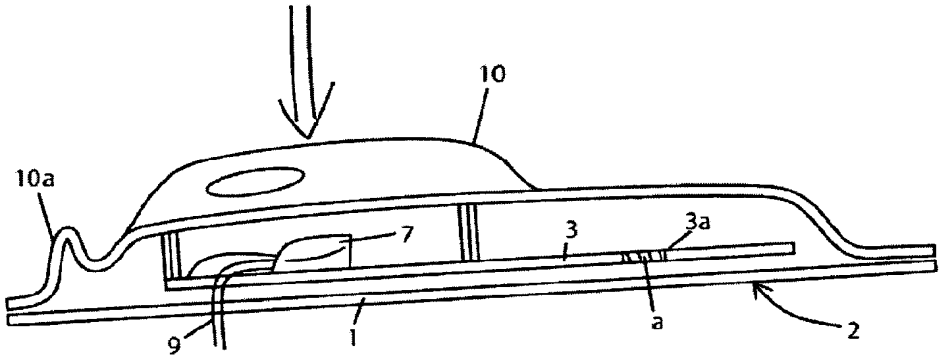

Fig. 3B

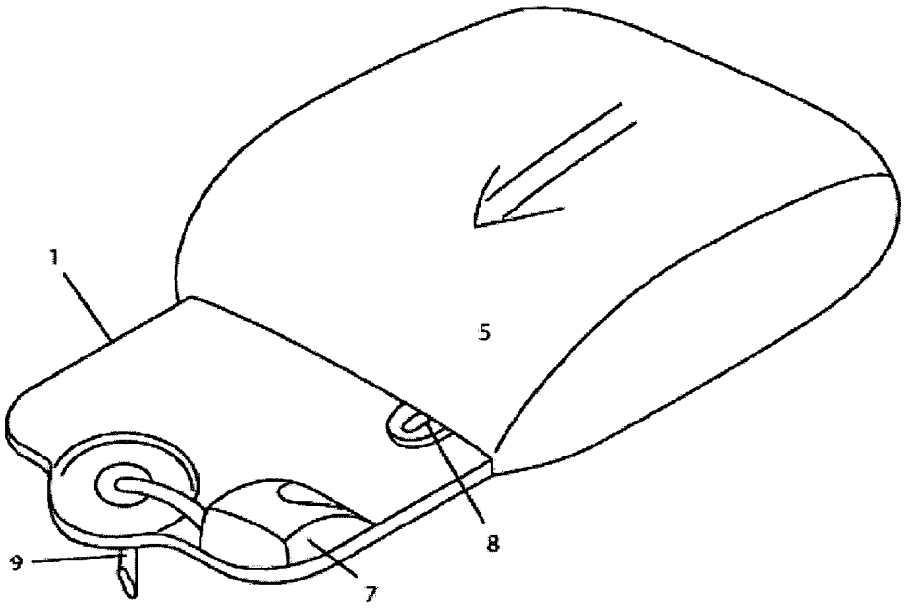

Fig. 4

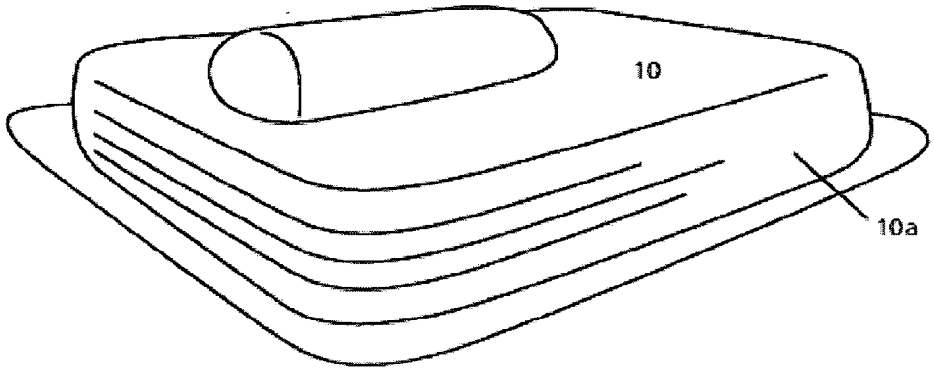

Fig. 5A

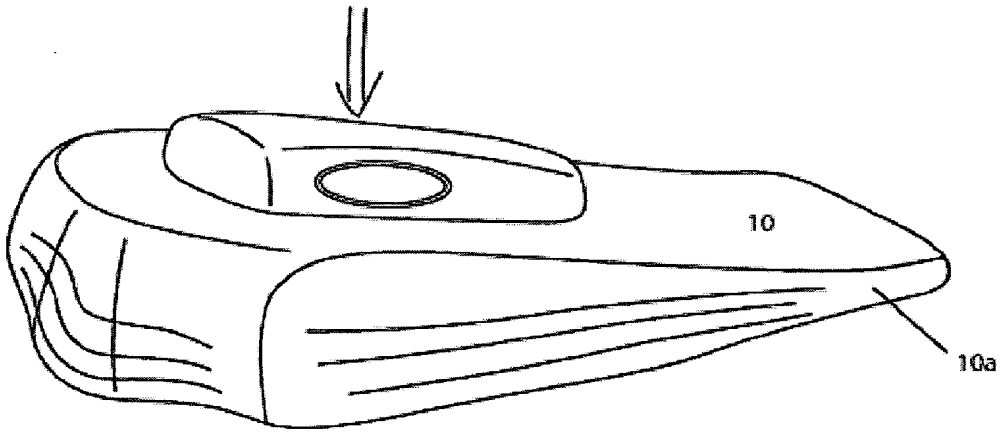

Fig. 5B

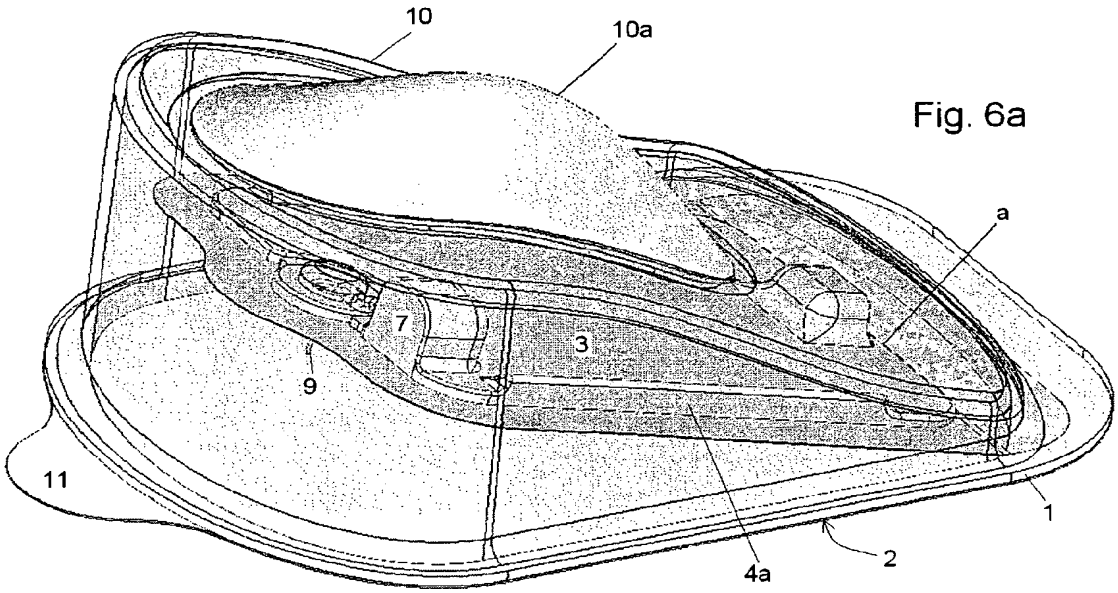

Fig. 6a

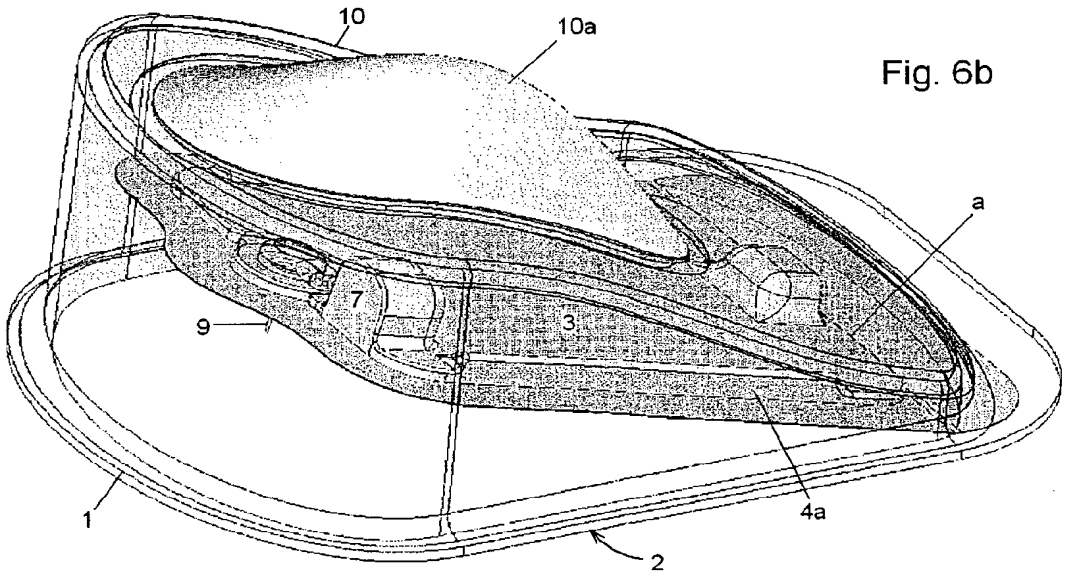

Fig. 6b

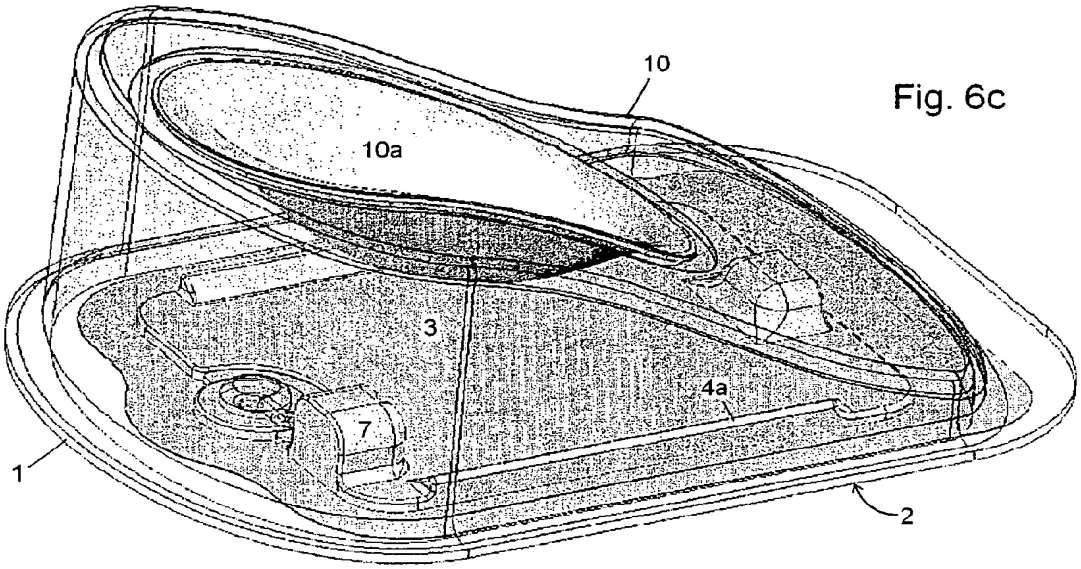

Fig. 6c

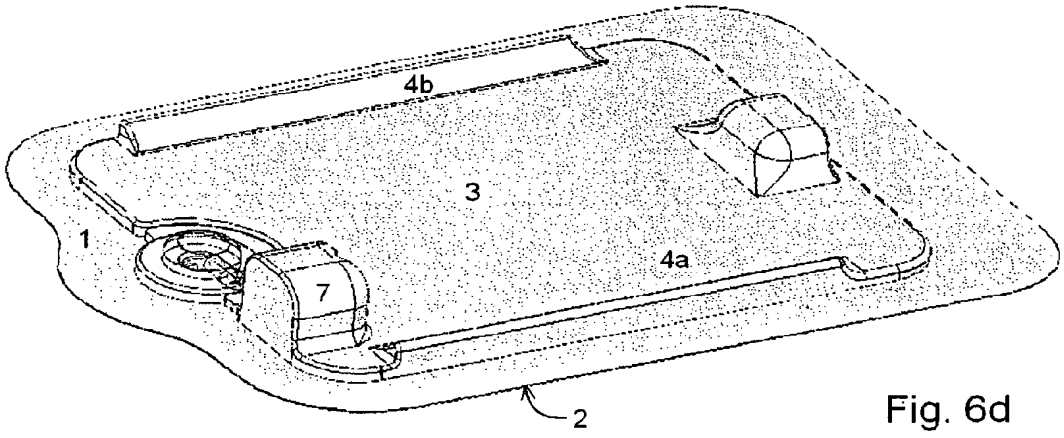

Fig. 6d

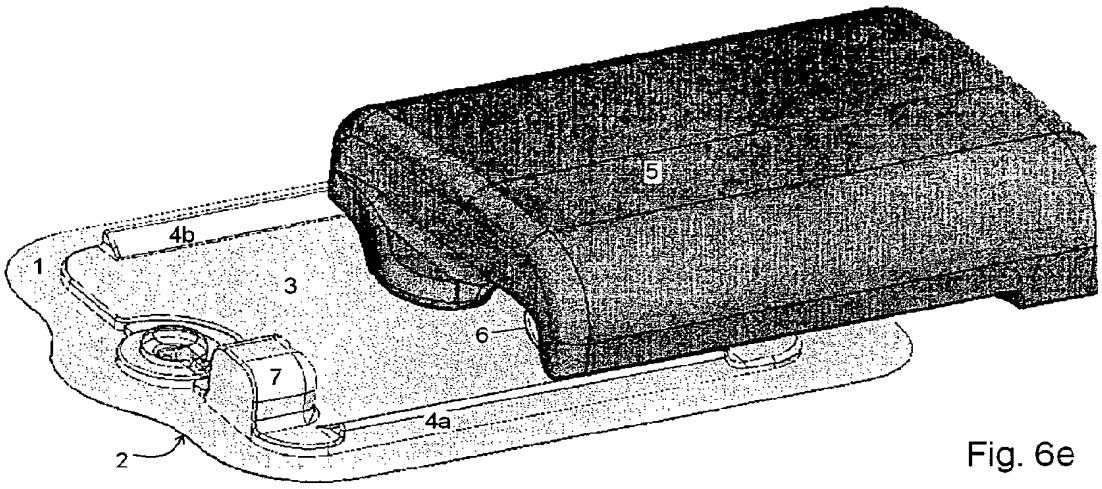

Fig. 6e

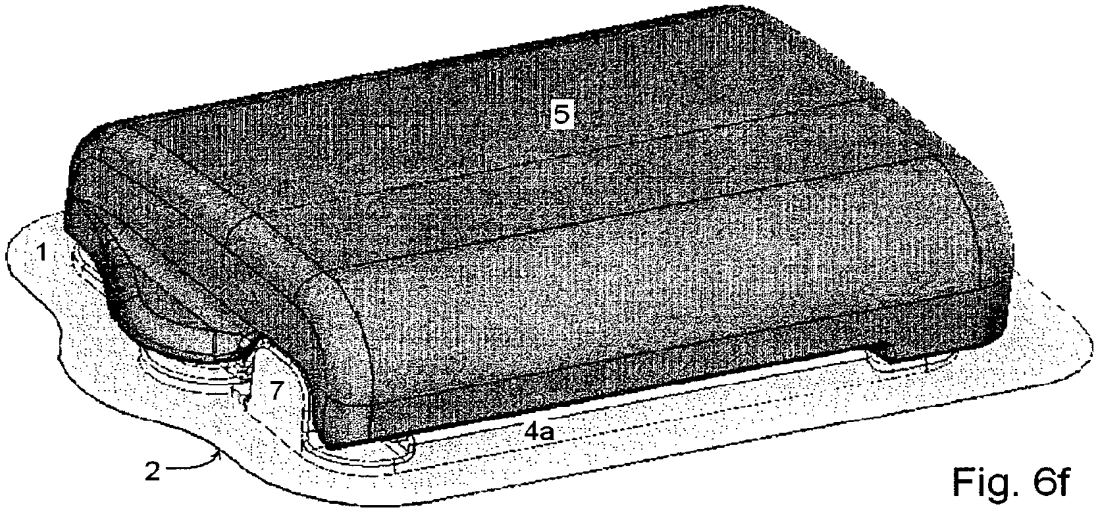

Fig. 6f

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/058379

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/142 A61M5/158

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/002649 A (NOVO NORDISK AS [DK]; RADMER JIM [DK]; KLINT HENRIK SOENDERSKOV [DK]) 13 January 2005 (2005-01-13) page 14, line 10 - page 19, line 14; figures 1a-6b	1-5,9-13
X	WO 2005/018703 A (BECTON DICKINSON CO [US]; CINDRICH CHRIS [US]; SONDEREGGER RALPH [US];) 3 March 2005 (2005-03-03) paragraphs [0199] - [0201]; figures 25-27	1-5,9-13
X	WO 03/095003 A (CAMBRIDGE BIOSTABILITY LTD [GB]; IDEA INC [US]; ROSER BRUCE [GB]) 20 November 2003 (2003-11-20) page 8, line 16 - page 12, line 19; figures 1a-2d abstract	1-5,9, 10,13

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
23 September 2009	30/09/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Jameson, Patricia

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/058379

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 755 805 B1 (REID ALAN [US]) 29 June 2004 (2004-06-29) column 1, line 55 - column 4, line 52; figures 1a-5b	1,5-9,11
X	WO 2007/093051 A (PKA SOFTTOUCH CORP [CA]; MODI PANKAJ [CA]) 23 August 2007 (2007-08-23) paragraphs [0031] - [0041]; figures 2a-j	1,9-11, 13
P,X	WO 2009/004026 A (UNOMEDICAL AS [DK]; GYRN STEFFEN [DK]; HASTED SOEREN BO [DK]; HAGEDORN) 8 January 2009 (2009-01-08) the whole document	1,2,9
A	EP 1 475 113 A (NOVO NORDISK AS [DK]) 10 November 2004 (2004-11-10) paragraphs [0040] - [0064]; figures 1-10	1-4,9, 10,13
A	WO 2004/098683 A (NOVO NORDISK AS [DK]; ETHELFELD ERIK WINKEL [DK]) 18 November 2004 (2004-11-18) page 12, line 6 - page 16, line 10; figures 1-7a	1,2,5, 10,13
A	EP 1 616 594 A (CLINICO GMBH [DE]) 18 January 2006 (2006-01-18) paragraphs [0030] - [0036]; compounds 1-5	1
A	WO 2007/002523 A (3M INNOVATIVE PROPERTIES CO [US]; FREDERICKSON FRANKLYN L [US]; JOHNSO) 4 January 2007 (2007-01-04) abstract; figures 1-3b	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/058379

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 2005002649	A	13-01-2005	EP	1495775 A1	12-01-2005
			US	2006200073 A1	07-09-2006
WO 2005018703	A	03-03-2005	AU	2004266650 A1	03-03-2005
			AU	2004266652 A1	03-03-2005
			BR	PI0413532 A	31-10-2006
			BR	PI0413538 A	10-10-2006
			BR	PI0413539 A	10-10-2006
			CA	2534726 A1	03-03-2005
			CA	2535138 A1	03-03-2005
			EP	1654022 A2	10-05-2006
			EP	1654017 A2	10-05-2006
			EP	1654018 A2	10-05-2006
			JP	2007518455 T	12-07-2007
			JP	2007502169 T	08-02-2007
			MX	PA06001370 A	15-05-2006
			MX	PA06001373 A	15-05-2006
			MX	PA06001467 A	15-05-2006
			SG	145737 A1	29-09-2008
			US	2008215015 A1	04-09-2008
			US	2005065466 A1	24-03-2005
			US	2005065472 A1	24-03-2005
			WO	2005018704 A2	03-03-2005
			WO	2005018705 A2	03-03-2005
WO 03095003	A	20-11-2003	AU	2003223720 A1	11-11-2003
			CA	2484817 A1	20-11-2003
			CN	1652834 A	10-08-2005
			EP	1506028 A1	16-02-2005
			KR	20050025179 A	11-03-2005
			RU	2300396 C2	10-06-2007
			US	2003212362 A1	13-11-2003
			ZA	200409474 A	28-06-2006
US 6755805	B1	29-06-2004	US	2009030371 A1	29-01-2009
			US	2009054848 A1	26-02-2009
			US	2004138613 A1	15-07-2004
WO 2007093051	A	23-08-2007	AU	2007215343 A1	23-08-2007
			CA	2536845 A1	16-08-2007
			EC	SP088681 A	31-10-2008
			EP	1983964 A1	29-10-2008
			JP	2009526575 T	23-07-2009
			US	2007191780 A1	16-08-2007
WO 2009004026	A	08-01-2009	NONE		
EP 1475113	A	10-11-2004	WO	2004098685 A1	18-11-2004
			US	2006095014 A1	04-05-2006
WO 2004098683	A	18-11-2004	AT	392223 T	15-05-2008
			DE	602004013140 T2	02-07-2009
			EP	1624914 A1	15-02-2006
			US	2006142698 A1	29-06-2006
EP 1616594	A	18-01-2006	AT	352343 T	15-02-2007
			DK	1616594 T3	29-05-2007
			US	2006015076 A1	19-01-2006

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/058379

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007002523 A	04-01-2007	EP 1904158 A2	02-04-2008
		US 2008195035 A1	14-08-2008